DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

May 7, 2015

Medacta International
Mr. Michael G. Loiterman
Director of Regulatory, Quality and Compliance
1556 W. Carroll Avenue
Chicago, Illinois 60607

Re: K142744
Trade/Device Name: Mecta-C TiPEEK
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: April 3, 2015
Received: April 6, 2015

Dear Mr. Loiterman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142744

K142744

Device Name
Mecta-C TiPEEK

Indications for Use *(Describe)*

The Mecta-C intervertebral body fusion device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation.

The Mecta-C device is intended for use at one level in the cervical spine, from C2-T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment prior to treatment with the device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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Date Prepared: April 28, 2015

DEVICE INFORMATION

Trade/Proprietary Name: Mecta-C TiPEEK
Classification Name: Intervertebral Body Fusion Device, Cervical
21 CFR 888.3080
Class II
Device Product Code(s): ODP

Primary Predicate Device:

510(k)	Product	510(k) Holder	Clearance Date
K112862	Mecta-C	Medacta International	12/19/2011

Additional Predicate Device:

510(k)	Product	510(k) Holder	Clearance Date
K133192	MectaLIF TiPEEK	Medacta International	1/30/2014

Product Description

The Mecta-C TiPEEK Intervertebral Body Fusion Devices are fusion devices intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the cervical spine. The Mecta-C TiPEEK intervertebral body fusion device is indicated for the treatment of degenerative diseases of the cervical disc and can be used for cervical fusion from C2-T1. The Mecta-C TiPEEK intervertebral body fusion device consists of a PEEK Implant Grade Polyetheretherketone (ASTM F 2026) body with a commercially pure titanium (CPTi, ASTM F 1580) coating and tantalum markers (ISO 13782 / ASTM F 560). The markers are placed in the implant on each end of the TiPEEK cages to allow easier radiological assessment of the position and orientation of the radiolucent TiPEEK cages. The cages are offered in various widths, heights, footprint geometries and lordosis which can be inserted between two cervical vertebra bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

Purpose

The purpose this submission is to add a CPTi coating as well as add an alternative PEEK material.

Indications for Use

The Mecta-C intervertebral body fusion device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation.
The Mecta-C device is intended for use at one level in the cervical spine, from C2-T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment prior to treatment with the device.

Comparison to Predicate Devices

The indications for use, design features and materials of the Mecta-C TiPEEK are substantially equivalent to those of the predicate devices. The substantial equivalence of the Mecta-C TiPEEK implants is supported by the performance testing, materials information, and data analysis provided within this Premarket Notification.

Performance Testing

Performance testing was conducted in accordance with FDA Guidance - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device as well as in accordance with FDA Guidance - Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements. Additional wear analysis for particulates was conducted and it was determined that Mecta-C TiPEEK passed all requirements.

Mecta-C TiPEEK was tested for wear analysis using the worst-case component size and option/design for each of the following standards:
Test Methods for Intervertebral Body Fusion Devices - ASTM F2077
Standard Practice for Characterization of Particles - ASTM F1877

The following mechanical tests were performed on the K112862 predicate device:
Static Axial Compression - ASTM F2077
Dynamic Axial Compression - ASTM F2077
Static Compression/Shear - ASTM F2077
Dynamic Compression/Shear - ASTM F2077
Static Torsion - ASTM F2077
Dynamic Torsion - ASTM F2077
Subsidence - ASTM F2267

Enzymatic digestion validation on titanium particulate testing was performed on the K133192 predicate device according to:
Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants - ASTM F1580

A review of the mechanical data indicates that the performance of the Mecta-C TiPEEK is substantially equivalent to the predicate devices and is capable of withstanding expected in vivo loading without failure.

Conclusion:

Based on the above information, the Mecta-C TiPEEK can be considered as substantially equivalent to its predicate devices.